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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1815	60

DATE MAILED: 11/25/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 8/25/97.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire — 1 — month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1,4-7,9-19,21-37,39,41-50,52,+54-61 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1,4-7,9-19,21-37,39,41-50,52,+54-61 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of ~~Reference Cited~~, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1815.

2. Claims 1, 4-7, 9-19, 21-37, 39, 41-50, 52, 54-58, 60 and 61 are pending in this application.

Lack of Unity

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

With respect to unity of invention PCT Rule 13.1 states:

> The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Additionally, PCT Rule 13.2 states:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

With regard to the application of PCT Rule 13, 37 CFR §1.475 concerning unity of invention states:

> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Group I, claim(s) 1-7, 26-29 and 41 drawn to a polynucleotides of HCV, encoded polypeptides, methods of making recombinant polypeptides and host cells.

Group II, claim(s) 9, 11, 16 and 21 drawn to oligonucleotide primers and methods of detecting HCV using the primer, and a kit comprising the primer.

Group III, claim(s) 10, and 12-15 drawn to oligonucleotide probes and and kits comprising the probe.

Group IV, claims 17 and 21 drawn to methods of detecting HCV nucleic acids in a sample using a primer and a probe.

Group V, claims 18 and 21 drawn to methods of detecting HCV genotypes in a sample using a primer.

Group VI, claim 19 drawn to methods of detecting HCV genotypes using a primer and a probe.

Group VII, claims 22-25, 32-36, 39, 41, 44, 45, 47-49, and 52 drawn to HCV polypeptides, kits comprising solely the polypeptides, pharmaceuticals comprising solely the polypeptides, and vaccines comprising solely the polypeptides.

Group VIII, claims 30 and 42 drawn to a method of detecting antibodies to HCV in a sample using the peptides of group VII.

Group IX, claims 31 and 43 drawn to a method of HCV typing a sample using the peptides of group VII.

Group X, claims 37 and 50 drawn to methods of preventing infection.

Group XI, claims 46 drawn to diagnostic kits comprising more than one polypeptide.

Group XII, claim 54, 57, 58, and 60 drawn to antibodies.

Group XIII, claim 55 drawn to a method of detecting HCV antigens.

Group XIV, claim 56 drawn to a method of HCV antigen typing.

Group XV claims 61 drawn to methods of preventing infection using an antibody.

4. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature unifying a set of different sequences. One particular sequence may have a special technical feature unifying that sequence with methods of making and using that sequence, but one HCV sequence does not predict another "previously unknown" sequence of HCV.

Therefore the HCV sequences are not a special technical feature as defined in PCT Rule 13.2.

Group I claims 1-7, 26-29 and 41 share the inventive concept of being drawn to polynucleotides of HCV, recombinant polypeptides encoded by those polynucleotides, and methods of making recombinant polypeptides.

Group II, claims 9, 11, 16 and 21 share the inventive concept of being drawn to a primer comprising an HCV sequence, a kit whose only component is the primer, and methods of detecting HCV sequences using that primer.

Group III, claims 10 and 12-15 share the inventive concept of being drawn to a polynucleotide probe comprising HCV sequences, and kits comprising those probes as the only component.

Group IV, claims 17 and 21 share the inventive concept of being drawn to a method of detecting HCV sequences wherein both a primer, and a probe are used in separate steps.

Group V, claims 18 and 21 share the inventive concept of being drawn to a method of identifying the genotype of an HCV sequence using a primer.

Group VI, claim 19 share the inventive concept of being drawn to a method of identifying the genotype of an HCV sequence using a primer and a probe used in separate steps.

Group VII, claims 22-25, 32-36, 39, 41, 44, 45, 47-49 and 52 share the inventive concept of being drawn to polypeptides comprising HCV sequences, kits comprising the polypeptide as the sole component, pharmaceutical compositions comprising the polypeptides as the sole component, and vaccines comprising the polypeptides as the sole component.

Group VIII, claims 30 and 42 share the inventive concept of being drawn to a method of detecting antibodies to HCV using a polypeptide.

Group IX, claims 31 and 43 share the inventive concept of being drawn to a method of determining the genotype of HCV by using a polypeptide.

Group X, claims 37 and 50 share the inventive concept of being drawn to a method of preventing infection using a polypeptide.

Group XI, claim 46 share the inventive concept of being drawn to a kit comprising more than one polypeptide.

Group XII, claims 54, 57, 58 and 60 share the inventive concept of being drawn to antibodies to HCV, kits comprising the antibody as the sole component, and a pharmaceutical comprising the antibody as the sole component.

Group XIII, claims 55 share the inventive concept of being drawn to a method of detecting HCV antigens using an antibody.

Group XIV, claims 56 share the inventive concept of being drawn to a method of determining the HCV genotype using an antibody.

Group XV, claims 61 share the inventive concept of being drawn to a method of preventing infection using an antibody.

The polynucleotides of group I are distinct from the primers and probes of groups II and III, because a primer has particular functional requirements for it to be designated a primer, that are not necessary for a polynucleotide, and a polynucleotide probe also has particular functional requirements that are not necessary for the designation of polynucleotide.

The polynucleotides of group I are distinct from the methods of groups IV-VI and all of the remaining groups, because the polynucleotides cannot all perform the necessary steps in the methods, and are not necessary for the production of the polypeptides or antibodies per se.

The primers of group II are distinct from the probes of groups III because primers and probes have differing functional requirements. A primer is generally short, and is chosen for use in "priming" DNA sequences, for example in PCR. While a primer may function as a probe, a probe will not adequately function as a primer. A probe is chosen for the broad detection of a sequence in a sample, and not for the priming of DNA synthesis.

The methods of genotyping HCV and the methods of detecting HCV used throughout the claims (groups IV, V, VI, VIII, IX, XII, and XIV) are distinct. A method that detects HCV does not necessarily have to tell you what the genotype of the HCV is. Genotyping generally requires a panel of reagents so that a particular genotype can be identified.

The methods of detecting or genotyping using one reagent (groups II, V, VIII, IX, XIII and XIV) are distinct from methods of detecting or genotyping using two reagents (groups IV and VI) as these are different methods having differing method steps, requiring differing reagents, and possibly producing differing results.

The polypeptides of group VII are distinct from groups I-VI and XII-XV as they are different chemical and/or biochemical entities.

The methods of preventing infection of group X is distinct from that of group XV as is uses a differing biochemical entity.

5. This application contains claims directed to the following patentably distinct species of the claimed invention of Group I: The examiner would like to be able to list the patentably distinct species of group I, and group VII, however the claims are incomprehensible as written. It is totally unclear as to what Applicant is directly claiming in claim 1. How the limitations of claim 2 affect the sequences of claim 1 is incomprehensible. The Examiner reviewed the specification and was unable to identify a single fully disclosed sequenced that meets the limitations of claim 1, or any of the other pending claims. The Examiner has reviewed the International Search Report issued in the corresponding PCT application, but discovered that Applicant has specifically excluded the searched sequences by amendment in this application.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: There is no special technical feature unifying a set of different sequences. One particular sequence may have a special technical feature unifying that

sequence with methods of making and using that sequence, but one HCV sequence does not predict another "previously unknown" sequence of HCV.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is required to specifically point out the support in the specification as filed for the elected species, which also must fully meet the limitations of the elected claims.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
November 18, 1997

MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800